

Remarks:

Claims 1 to 10 and 17, 18, and 21 to 31 remain in the application. Claims 1, 21, and 22 have been amended. Claims 11 to 16 and 19 to 20 were canceled in a previous amendment to facilitate prosecution of the instant application.

Initially, it is noted that claim 22 has been amended to correct two typographical errors. These changes are not made to overcome any prior art or for any reason related to patentability. These changes are merely made for cosmetic reasons.

In items 1 to 4 on pages 2 to 3 of the above-identified Office action, claims 1, 5 to 10, and 21 have been rejected as being fully anticipated by U.S. 3,851,359 to Wilson under 35 U.S.C. § 102.

The rejection has been noted and claims 1 and 21 have been amended in an effort to even more clearly define the invention of the instant application. Support for the changes is found, for example, in FIGS. 19, 21, and 22 of the instant application.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful.

Claim 1 calls for, *inter alia*, a surgical clip, including:

at least one deformable retainer extending past one end of said arms in a direction, wherein the retainer has a length in the direction of at least approximately n times the distance between the arms when the arms are substantially parallel.

Claim 21 calls for, *inter alia*, a surgical clip, including:

at least one deformable retainer extending past one end of said arms in a direction, the retainer having a length in the direction equal to a multiple of a distance between the arms, the multiple being greater than 2.5.

Wilson discloses a safety pin "of the type normally used for fastening to fabrics and clothing . . . such as securing diapers on babies." Wilson at col. 1, lines 5 to 9. Wilson's safety pin is made to close easily. See Wilson at col. 3, lines 15 to 33. However, to remove the safety pin, the frangible portion 10d must be **broken** -- rendering the remaining pin parts unusable. See Wilson at col. 3, lines 33 to 40. Wilson does not disclose or suggest *surgical* use of Wilson's 1973 variation of the commonly used safety pin.

The Examiner states that the structure analogous to the first arm is leg portion 10a, to the second arm is leg portion 10b, and to the bridge is transition bend 10c. The Examiner further states that Wilson's deformable retainer is the head 11 of the safety pin. As described with respect to FIGS. 5 and 6 in Wilson, the only aspect of the safety pin that deforms in the head 11 is the resiliently deformable flap 11c -- unless the frangible portion 10d (not a part of the head 11) is deemed to be counted as a deformable retainer, which, applicants believe, is not a viable alternative. Nonetheless, the Examiner has continued the belief that the retainer in Wilson corresponds to the *entirety* of the head 11.

The Examiner admits that the distance between the two parallel arms 10a, 10b is 9.5 mm as measured in the drawings.

If the flap 11c was considered to be the retainer as submitted by Applicants, it is (without the need for measurement) not greater than the distance between the arms 10a, 10b.

Therefore, the flap 11c cannot be considered as having a length greater than the distance between the arms when the arms are substantially parallel as set forth in claim 1 (see also claim 21).

The Examiner indicates that the length of the retainer -- head 11 -- is 18.5 mm. Accordingly, the 18.5 mm retainer 11 *is not even two times* the arm separation distance and, therefore, cannot be considered to be more than 2.5 or 3.14159 times the 9.5 mm arm distance.

Clearly, Wilson does not show a clip as recited in claims 1 or 21 of the instant application.

Insofar as claims 1 and 21 are allowable, and due to the fact that claims 2 through 10 ultimately depend upon claim 1, these claims are allowable as well.

In items 5 to 8 on pages 3 to 4 of the above-identified Office action, claims 1, 2, 4, 5, and 21 to 26 have been rejected as being fully anticipated by U.S. 5,575,802 to McQuilken et al. (hereinafter "McQuilken") under 35 U.S.C. § 102.

As will be explained below, it is believed that these claims were patentable over McQuilken in their original form and, therefore, the claims have not been amended to overcome McQuilken.

Claim 1 calls for, *inter alia*, a surgical clip, including:

a bridge connecting first and second arms to form a substantially U-shaped structure; and

at least one deformable retainer extending past one end of the arms in a direction, wherein the retainer has a length in the direction of at least approximately  $\pi$  times the distance between the arms when the arms are substantially parallel.

Claim 21 calls for, *inter alia*, a surgical clip, including:

a bridge connecting the first and second arms to form a substantially U-shaped structure with the first and second arms being substantially parallel to one another; and

at least one deformable retainer extending past one end of the arms in a direction, the retainer having a length in the direction equal to a multiple of a distance between the arms, the multiple being greater than 2.5.

Claim 22 calls for, *inter alia*, a surgical clip, including:

a bridge connecting first and second arms to form a substantially U-shaped structure.

McQuilkin discloses a medical clip "suitable for sexual sterilization." See Abstract and col. 1, lines 3 to 6. FIG. 1 illustrates the medical clip in the opened position and FIGS. 2 and 3 illustrate the clip in the closed and closed-and-fastened positions, respectively.

Because the clip is to be clamped upon a Fallopian tube or vas deferens to effect occlusion, direct contact between the silicone rubber lining 18, 20 of the jaws 12, 14 is required. In other words, the distance between the jaws 12, 14 is equal to **zero**. Therefore, the McQuilkin retainer cannot have a length of greater than 2.5 or  $\pi$  "times the distance between the arms when the arms are substantially parallel" as set forth in claims 1 (see also claim 21).

The McQuilkin jaws 12, 14 are not parallel when in the non-applied (open) position and are parallel only when the clip is in the occluding (closed) position. Accordingly, McQuilkin does not and cannot teach two arms having a "distance between the arms when the arms are substantially parallel" to one another as set forth in claims 1, 17, 21, and 22.

Claims 1, 21, and 22 provide that "a bridge connect[s] said first and second arms to form a substantially U-shaped

structure." By definition, a "U-shaped structure" requires some distance between the two arms of the U-shape. If there is no distance, then it cannot be considered U-shaped. When the two jaws 12, 14 are parallel, McQuilken has no separation distance therebetween. Therefore, the McQuilken clip cannot be considered U-shaped and, accordingly, cannot anticipate claims 1, 21, or 22.

The Examiner sets forth argument that the liner 18, 20 is separate from the jaws 12, 14. However, the liner 18, 20, while being of a different material, is non-removably connected to the jaws 12, 14 and is not separate from the jaws 12, 14. McQuilken cannot achieve its intended purpose unless the distance between the jaws 12, 14, 18, 20 is equal to ZERO because it would not isolate the clamped tissue therebetween. Thus, the McQuilkin clip is not a U-shaped structure.

Clearly, McQuilkin does not show a surgical clip as recited in claims 1, 21, or 22 of the instant application.

Insofar as claims 22 is allowable, and due to the fact that claims 23 through 31 ultimately depend upon claim 22, these claims are allowable as well.

In items 9 to 10 on page 4 of the above-identified Office action, claims 1, 5, 6, 22, 26, and 27 have been rejected as being fully anticipated by U.S. 2,246,495 to Alessi, et al. (hereinafter "Alessi") under 35 U.S.C. § 102.

Alessi discloses a variation of a common safety pin.

The Examiner states that "Alessi discloses a clip *capable of use in surgery*. . ." Upon review of the Alessi specification, the only mention of use for the safety pin relates to the same use that is made by a "safety pin of the type in common use." Alessi at page 1, lines 4 to 5 and 22 to 24 left column, for example. Nowhere does Alessi disclose or suggest *surgical* use of Alessi's 1938 variation of the commonly used safety pin.

Alessi discloses a device for retaining the swiveling pin member 10 with respect to the tubular guard 15. Each mention of the pin member 10 in the patent describes the member 10 as being rigid. For example, page 1, lines 4 to 9 right column, provides that only "**abnormal** distortion by exceptional stress will be required to divert the pointed end of the pin out of range of the guard." (Emphasis added by applicants.) Page 1, lines 17 to 19 right column, provides "a relatively rigid pin member to achieve substantial **inherent resistance to flexure**."



(Emphasis added by applicants.) Simply put, the Alessi pin member 10 is not flexible, let alone deformable.

The tubular guard 15 is not envisioned to bend or deform. The only aspect of the Alessi safety pin that does deform is the torsional spring 21. This spring 21 has a length that is, in some embodiments (FIGS. 1, 3, 4), barely equal to the distance between the parallel first and second tubular portions 16, 17. FIG. 5 shows the spring 40 slightly greater than the distance between the parallel first and second tubular portions 16, 17. In no way does either spring 21, 40 have "a length of at least approximately  $n$  times the distance between the arms [16, 17] when the arms are substantially parallel" as set forth in claims 1 or 22. Even if one could consider the first portion 16 as part of a deforming retainer, the combined distance is no greater than twice the distance between the arms 16, 17.

The Examiner contends that the "deformable retainer" comprises the tubular portion 16, the spring 21, and the guard 15. Applicant respectfully disagrees. The word "deform" can be defined as "to spoil the natural form of," "to mar the appearance of," or "to alter the shape of by pressure or stress." The tubular portion 16 and the guard 15 do not deform; only the spring 21 deforms.

Even if one could agree that the tubular portion 16, the spring 21, and the guard 15 **all** deform, and, therefore, could be considered analogous to the retainer of claims 1 or 22, then the length of this so-called "retainer" does not anticipate the retainer of claim 1 the instant application. Specifically, the greatest length of a retainer in the direction extending from the end of an arm can be defined by the bottom level of the spring 21 in FIG. 5 and the top most surface of the guard 15 measured perpendicular to the longitudinal axis of the arm 11. This distance is no greater than 30 mm. In comparison, the distance between leg 11 and leg 12 is 16 mm. Thus, length of the "retainer" in Alessi is even *less than twice* the distance between the legs 11, 12 and, in particular, is less than 2.5 times this distance.

Clearly, Alessi does not show a surgical clip as recited in claims 1 or 22 of the instant application.

Insofar as claims 1 and 22 are allowable, and due to the fact that claims 5, 6, 26, and 27 ultimately depend upon claims 1 or 22, these claims are allowable as well.

In item 11 on pages 4 to 5 of the above-identified Office action, claims 17 and 18 have been rejected as being fully

anticipated by U.S. 4,430,997 to DiGiovanni et al.  
(hereinafter "DiGiovanni") under 35 U.S.C. § 102.

As will be explained below, it is believed that the claims were patentable over the cited art in their original form and, therefore, the claims have not been amended to overcome the references.

DiGiovanni discloses a multiple clip applier used to apply clips like those in McQuilkin. See, in particular, FIG. 2A of DiGiovanni. Therefore, all of the arguments with respect to McQuilkin are applicable to distinguish DiGiovanni and are hereby incorporated by reference. It is particularly noted that the clips are set "to ligate a vessel," are set "about the vessel to be ligated" and/or are "set to ligate the vessel." See DiGiovanni at col. 1, line 15, col. 2, lines 5, 31, and 40, respectively. Thus, the arms have a zero distance when parallel.

Clearly, DiGiovanni does not show a surgical clip as recited in claim 17 of the instant application.

Insofar as claims 17 is allowable, and due to the fact that claim 18 ultimately depends upon claim 17, this claim is allowable as well.

In item 12 on pages 5 to 6 of the above-identified Office action, claims 1, 3, 22, 23, and 28 have been rejected as being fully anticipated by U.S. 2004/0104199 A1 to Chen under 35 U.S.C. § 102.

As will be explained below, it is believed that the claims were patentable over the cited art in their original form and, therefore, the claims have not been amended to overcome the references.

Chen is a paper clip formed from repeating rectangular coils of metal wire. The Examiner contends that no structure is given to the word "retainer" in claims 1 or 22. Applicants respectfully disagree.

Claim 1 calls for, *inter alia*, a surgical clip, including:

at least one deformable retainer extending past one end of said arms in a direction, wherein  
said retainer has a length in said direction of at least approximately n times the distance between the arms when the arms are substantially parallel.

Claim 22 calls for, *inter alia*, a surgical clip, including:

at least one deformable retainer extending from one of the arms and having a deformable portion, the deformable portion of the retainer having a length of at least approximately  $\Pi$  times the distance between the arms when the arms are substantially parallel.

This structure is neither disclosed nor suggested by Chen.

Because the Examiner indicates that entirety of the Chen paper clip is deformable, the entire length of this paper clip is being compared to the retainer of claims 1 and 22.

Clearly, Chen does not show a clip as recited in claims 1 or 22 of the instant application.

Insofar as claims 1 and 22 are allowable, and due to the fact that claims 3, 23, and 28 ultimately depend upon claims 1 or 22, these claims are allowable as well.

Finally, applicant(s) appreciatively acknowledge(s) the Examiner's statement that claims 29 to 31 "would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." In

light of the above, applicants respectfully believe that rewriting of claims 29 to 31 is unnecessary at this time.

In view of the foregoing, reconsideration and allowance of claims 1 to 10 and 17, 18, and 21 to 31 are solicited.

In the event the Examiner should still find any of the claims to be unpatentable, counsel would appreciate receiving a telephone call so that, if possible, patentable language can be worked out.

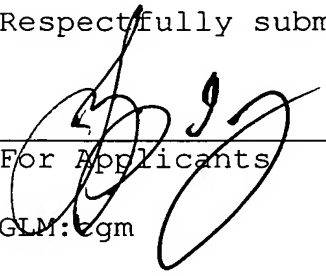
If an extension of time for this paper is required, petition for extension is herewith made.

The extension fee for response within a period of two (2) months pursuant to Section 1.136(a) in the amount of \$430.00 in accordance with Section 1.17 is enclosed herewith.

Applic. No. 10/010,246  
Response Dated November 9, 2004  
Responsive to Office Action of June 23, 2004

Please charge any other fees that might be due with respect to  
Sections 1.16 and 1.17 to the Deposit Account of Lerner and  
Greenberg, P.A., No. 12-1099.

Respectfully submitted,

  
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For Applicants

GLM:zgm

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